DRAFT 10/2/15

GENERAL GOVERNMENT CABINET
BOARD OF NURSING
(AMENDMENT)

201 KAR 20:057. Scope and standards of practice of advanced practice registered nurses.

RELATES TO: KRS 218A.205(3)(a), 314.011(7), 314.011(8), 314.042, 314.193(2), 314.196

STATUTORY AUTHORITY: KRS 218A.205(3)(a), 314.131(1), 314.193(2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.205(3)(a) requires the Board of Nursing to establish by administrative regulation mandatory prescribing and dispensing standards for licensees authorized to prescribe or dispense controlled substances. KRS 314.131(1) authorizes the board to promulgate administrative regulations necessary to enable it to carry into effect the provisions of KRS Chapter 314. KRS 314.193(2) authorizes the board to promulgate administrative regulations establishing standards for the performance of advanced practice registered nursing to safeguard the public health and welfare. This administrative regulation establishes the scope and standards of practice for an advanced practice registered nurse.

Section 1. Definitions. (1) "Collaboration" means the relationship between the advanced practice registered nurse and a physician in the provision of prescription medication, including both autonomous and cooperative decision-making, with the advanced practice registered nurse and the physician contributing their respective expertise.

(2) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances" or "CAPA-CS" means the written document pursuant to KRS 314.042(10).

(3) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs" or "CAPA-NS" means the written document pursuant to KRS 314.042(8).

(4) “KASPER” means the Kentucky All Schedule Prescription Electronic Reporting system established in KRS 218A.202.

Section 2. (1) The practice of the advanced practice registered nurse shall be in accordance with the standards and functions defined in scope and standards of practice statements adopted by the board in subsection (2) of this section.

(2) The following scope and standards of practice statements shall be adopted:

(a) AACN Scope and Standards for Acute Care Nurse Practitioner Practice;

(b) AACN Scope and Standards for Acute and Critical Care Clinical Nurse Specialist Practice;

(c) Neonatal Nursing: Scope and Standards of Practice;
(d) Nursing: Scope and Standards of Practice;
(e) Pediatric Nursing: Scope and Standards of Practice;
(f) Psychiatric-Mental Health Nursing 2nd Edition: Scope and Standards of Practice;
(g) Scope of Practice for Nurse Practitioners;
(h) Standards of Practice for Nurse Practitioners;
(i) Scope of Nurse Anesthesia Practice;
(j) Standards for Nurse Anesthesia Practice;
(k) Standards for Office Based Anesthesia Practice;
(l) Standards for the Practice of Midwifery;
(m) Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice; and
(n) The Women's Health Nurse Practitioner: Guidelines for Practice and Education.

Section 3. In the performance of advanced practice registered nursing, the advanced practice registered nurse shall seek consultation or referral in those situations outside the advanced practice registered nurse's scope of practice.

Section 4. Advanced practice registered nursing shall include prescribing medications and ordering treatments, devices, and diagnostic tests which are consistent with the scope and standard of practice of the advanced practice registered nurse.

Section 5. Advanced practice registered nursing shall not preclude the practice by the advanced practice registered nurse of registered nursing practice as defined in KRS 314.011(6).

Section 6. (1)(a) A CAPA-NS and a CAPA-CS shall include the name, address, phone number, and license number of both the advanced practice registered nurse and each physician who is a party to the agreement. It shall also include the specialty area of practice of the advanced practice registered nurse.
(b) Pursuant to KRS 314.196(2), an advanced practice registered nurse shall use the Common CAPA-NS Form.
(2)(a) To notify the board of the existence of a CAPA-NS pursuant to KRS 314.042(8)(b), the APRN shall file with the board the Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs (CAPA-NS).
(b) To notify the board that the requirements of KRS 314.042(9) have been met and that the APRN will be prescribing nonscheduled legend drugs without a CAPA-NS, the APRN shall file the Notification to Discontinue the CAPA-NS After Four Years.

(c) To notify the board of the existence of a CAPA-CS pursuant to KRS 314.042(10)(b), the APRN shall file with the board the Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS).

(3) For purposes of the CAPA-NS and the CAPA-CS, in determining whether the APRN and the collaborating physician are qualified in the same or a similar specialty, the board shall be guided by the facts of each particular situation and the scope of the APRN's and the physician's actual practice.

(4)(a) An APRN with a CAPA-CS shall report all of his or her United States Drug Enforcement Agency (DEA) Controlled Substance Registration Certificate numbers to the board when issued to the APRN by mailing a copy of each registration certificate to the board within thirty (30) days of issuance.

(b) Any change in the status of a DEA Controlled Substance Registration Certificate number shall be reported in writing to the board within thirty (30) days.

Section 7. Prescribing medications without a CAPA-NS or a CAPA-CS shall constitute a violation of KRS 314.091(1), except when a CAPA-NS has been discontinued pursuant to KRS 314.042(9) or the provisions of KRS 314.196(4)(b) apply.

Section 8. The board may make an unannounced monitoring visit to an advanced practice registered nurse to determine if the advanced practice registered nurse's practice is consistent with the requirements established by KRS Chapter 314 and 201 KAR Chapter 20, and patient and prescribing records shall be made available for immediate inspection.

Section 9. Prescribing Standards for Controlled Substances. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance [~~other than a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone~~]. It also applies to the utilization of KASPER.

(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus. This section does not alter the prescribing limits set out in KRS 314.011(8).

(2) [~~This section shall not apply to:~~

~~(a) An APRN prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;~~

~~(b) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or~~

~~(c) An APRN prescribing a controlled substance:~~

~~1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional~~

~~account, if the hospital, long-term-care facility, or licensee queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;~~

~~2. As part of the patient's hospice or end-of-life treatment;~~

~~3. For the treatment of pain associated with cancer or with the treatment of cancer;~~

~~4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;~~

~~5. Within seven (7) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing:~~

~~a. Is done as a substitute for the initial prescribing;~~

~~b. Cancels any refills for the initial prescription; and~~

~~c. Requires the patient to dispose of any remaining unconsumed medication;~~

~~6. Within ninety (90) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same [medical] condition;~~

~~7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health;~~

~~8. During the effective period of any disaster or situation with mass casualties that have a direct impact on the APRN's practice;~~

~~9. Administering or prescribing controlled substances to prisoners in a state, county, or municipal correctional facility; or~~

~~10. Prescribing a Schedule IV controlled substance for no longer than three (3) days for an established patient to assist the patient in responding to the anxiety of a nonrecurring event[; or~~

~~11. That has been classified as a Schedule V controlled substance.~~

~~(3)]~~ Prior to the initial prescribing of a controlled substance to a patient, the APRN shall [~~The APRN shall, prior to initially prescribing a controlled substance for a medical complaint for a patient~~]:

(a) Obtain the patient's medical history and conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient and maintain copies of these records in the patient's record;

(c) Make a written treatment plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate:

1. The risks and benefits of the use of controlled substances, including the risk of tolerance and drug dependence;

2. That the controlled substance shall be discontinued when the condition requiring its use has resolved; and

3. Document that the discussion occurred and obtain written consent for [~~that the patient consented to~~] the treatment.

(4) The treatment plan shall include an exit strategy, if appropriate, including potential discontinuation of the use of controlled substances.

(5) For subsequent or continuing long-term prescriptions of a controlled substance for the same medical complaint, the APRN shall:

(a) Update the patient's medical history and document the information in the patient's medical record;

(b) Modify the treatment plan as clinically appropriate; and

(c) Discuss the risks and benefits of any new controlled substances prescribed with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence.

(6) During the course of treatment, the APRN shall query KASPER no less than once every three (3) months for all available data on the patient before issuing a new prescription or a refill for a controlled substance. The APRN shall maintain copies in the patient's record.

(7) These requirements may be satisfied by other licensed practitioners in a single group practice if:

(a) Each licensed practitioner involved has lawful access to the patient's medical record;

(b) Each licensed practitioner performing an action to meet these requirements is acting within the scope of practice of his or her profession; and

(c) There is adequate documentation in the patient's medical record reflecting the actions of each practitioner.

(8) If prescribing a controlled substance for the treatment of chronic, noncancer pain, the APRN, in addition to the requirements of this section, shall obtain a baseline drug screen or further random drug screens if the APRN:

(a) Finds a drug screen to be clinically appropriate; or

(b) Believes that it is appropriate to determine whether or not the controlled substance is being taken by the patient.

(9) If prescribing a controlled substance for the treatment of a mental health condition, the APRN shall meet the requirements of this section.

(10)[~~If prescribing a controlled substance for a patient younger than sixteen (16) years of age, the APRN shall obtain and review an initial KASPER report. If~~

~~prescribing a controlled substance for an individual sixteen (16) years of age or older, the requirements of this section shall apply.~~

~~(11)~~] Prior to prescribing a controlled substance for a patient in the emergency department of a hospital that is not an emergency situation [~~as specified in subsection (2) of this section~~], the APRN shall:

(a) Obtain the patient's medical history, conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient;

(c) Make a written treatment plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence, and document that the discussion occurred and that the patient consented to the treatment.

(11) For each patient for whom an APRN prescribes a controlled substance, the APRN shall keep accurate, readily accessible, and complete medical records, which include:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed;

(h) Instructions and agreements;

(i) Periodic reviews of the patient's file; and

(j) KASPER records.

(12) The requirement to query KASPER shall not apply to:

(a) An APRN prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;

(b) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or

(c) An APRN prescribing a controlled substance:

1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER for all

available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. To assist a patient when presenting for a diagnostic test or procedure;

5. Within seven (7) days of an initial prescription pursuant to subsection (1) of this section if the prescribing:

a. Is done as a substitute for the initial prescribing;

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescription pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same [~~medical~~] condition;

7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health;

8. During the effective period of any disaster or situation with mass casualties that have a direct impact on the APRN's practice;

9. Administering or ordering controlled substances to prisoners in a state, county, or municipal correctional facility; or

10. Prescribing a Schedule IV controlled substance for no longer than three (3) days for an established patient to assist the patient in responding to the anxiety of a nonrecurring event.

(13) Federal regulation 21 CFR 1306.12(b) concerning the issuance of multiple prescriptions for Schedule II controlled substances shall not be utilized by APRNs in this state.

(14) An APRN may order a reverse KASPER report to review their prescribing practices and to verify the information contained in KASPER is correct.

Section 10. [~~Prescribing Standards for Controlled Substances from Schedule II and Schedule III Containing Hydrocodone. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance from Schedule II or Schedule III controlled substance containing hydrocodone. It also applies to the utilization of the Kentucky All Schedule Prescription Electronic Reporting system (KASPER).~~

~~(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus. This section does not alter the prescribing limits set out in KRS 314.011(8).~~

~~(2) This section shall not apply to:~~

~~(a) An APRN prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;~~

~~(b) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or~~

~~(c) An APRN prescribing a controlled substance:~~

~~1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;~~

~~2. As part of the patient's hospice or end-of-life treatment;~~

~~3. For the treatment of pain associated with cancer or with the treatment of cancer;~~

~~4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;~~

~~5. Within seven (7) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing or dispensing:~~

~~a. Is done as a substitute for the initial prescribing;~~

~~b. Cancels any refills for the initial prescription; and~~

~~c. Requires the patient to dispose of any remaining unconsumed medication;~~

~~6. Within ninety (90) days of an initial prescribing pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or~~

~~7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.~~

~~(3) Prior to the initial prescribing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, an APRN shall:~~

~~(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;~~

~~(b) Query the electronic monitoring system established in KRS 218A.202 for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;~~

~~(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;~~

~~(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and~~

~~(e) Obtain written consent for the treatment.~~

~~(4)(a) An APRN prescribing an additional amount of a Schedule II controlled substance or Schedule III controlled substance containing hydrocodone for the same medical complaint and related symptoms shall:~~

~~1. Review the plan of care at reasonable intervals based on the patient's individual circumstances and course of treatment;~~

~~2. Provide to the patient any new information about the treatment; and~~

~~3. Modify or terminate the treatment as appropriate.~~

~~(b) If the course of treatment extends beyond three (3) months, the licensee shall:~~

~~1. Query KASPER no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and~~

~~2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.~~

~~(5) For each patient for whom an APRN prescribes a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the licensee shall keep accurate, readily accessible, and complete medical records, which include, as appropriate:~~

~~(a) Medical history and physical or mental health examination;~~

~~(b) Diagnostic, therapeutic, and laboratory results;~~

~~(c) Evaluations and consultations;~~

~~(d) Treatment objectives;~~

~~(e) Discussion of risk, benefits, and limitations of treatments;~~

~~(f) Treatments;~~

~~(g) Medications, including date, type, dosage, and quantity prescribed;~~

~~(h) Instructions and agreements; [and]~~

~~(i) Periodic reviews of the patient's file; and~~

~~(j) KASPER records.~~]

[~~Section 11.~~] Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "AACN Scope and Standards for Acute Care Nurse Practitioner Practice", 2012 Edition, American Association of Critical-Care Nurses;

(b) "AACN Scope and Standards for Acute and Critical Care Clinical Nurse Specialist Practice", 2014 [~~2010~~] Edition, American Association of Critical-Care Nurses;

(c) "Neonatal Nursing: Scope and Standards of Practice", 2013 Edition, American Nurses Association/National Association of Neonatal Nurses;

(d) "Nursing: Scope and Standards of Practice", 2015 [~~2010~~] Edition, American Nurses Association;

(e) "Pediatric Nursing: Scope and Standards of Practice", 2008 Edition, American Nurses Association/Society of Pediatric Nursing/National Association of Pediatric Nurse Practitioners;

(f) "Psychiatric-Mental Health Nursing 2nd Edition: Scope and Standards of Practice", 2014, American Nurses Association/American Psychiatric Nursing Association;

(g) "Scope of Practice for Nurse Practitioners", 2013 Edition, American Association of Nurse Practitioners;

(h) "Standards of Practice for Nurse Practitioners", 2013 Edition, American Association of Nurse Practitioners;

(i) "Scope of Nurse Anesthesia Practice", 2013 Edition, American Association of Nurse Anesthetists;

(j) "Standards for Nurse Anesthesia Practice", 2013 Edition, American Association of Nurse Anesthetists;

(k) "Standards for Office Based Anesthesia Practice", 2015 [~~2013~~] Edition, American Association of Nurse Anesthetists;

(l) "Standards for the Practice of Midwifery"; 2011 Edition, American College of Nurse-Midwives;

(m) "Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice", 2013 Edition, Oncology Nursing Society;

(n) "The Women's Health Nurse Practitioner: Guidelines for Practice and Education", 2014 [~~2008~~] Edition, Association of Women's Health, Obstetric and Neonatal Nurses/Nurse Practitioners in Women's Health;

(o) "Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS)", 12/2014, Kentucky Board of Nursing;

(p) "Notification of a Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs (CAPA-NS)", 12/2014, Kentucky Board of Nursing; [~~and~~]

(q) "Notification to Discontinue the CAPA-NS After Four Years", 8/2015 [~~12/2014~~], Kentucky Board of Nursing; and

(r) "Common CAPA-NS Form", 6/2015.

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